K141093
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MAY 15 2014

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 25, 2014
Submitter:	GE Healthcare, GE Vingmed Ultrasound AS Strandpromenaden 45 N-3191, Horten, Norway
Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. Phone: 414-721-4214 Fax: 414-918-8275
Device: Trade Name:	6VT-D Ultrasound Transducer
Common/Usual Name:	6VT-D Ultrasound Transducer
Classification Names:	Diagnostic Ultrasound Transducer, 21 CFR 892.1570
Product Code:	90-ITX
Predicate Device(s):	K131514 GE Vivid E9 Diagnostic Ultrasound System including 6VT-D transducer. K060907 Karl Storz Video Gastroscope System
Device Description:	The 6VT-D is an ultrasound-imaging device that is attached to a GE ultrasound imaging system and used for diagnostic imaging. 6VT-D does not directly control energy delivered to the patient nor does it contain any software. The 6VT-D is a transducer for imaging cardiac anatomy in adults with transesophageal means of access. The objective of this 510(k) submission is to present the proposed modifications to the 6VT-D Transducer (K131514), and to demonstrate substantial equivalence. The 6VT-D transducer modification is an incremental improvement where one patient contact material of the endoscope is replaced by another. Both the current endoscope material, and the proposed new material, were evaluated for biocompatibility according to the same international standards, and both were found to be acceptable for the transducer's intended use and relevant patient contact. No design inputs are affected by the change of material.

Intended Use: The device is intended for use by a qualified physician for use with GE Diagnostic Ultrasound Systems for ultrasound evaluation of Cardiac anatomy of adults in 2D modes as well as in real-time 3D / 4D mode.

Technology: The 6VT-D Transducer employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The 6VT-D Diagnostic Ultrasound Transducer is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The 6VT-D is identical to the predicate 6VT-D transducer with respect to imaging and applications.
- The transducers are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The endoscope of 6VT-D uses identical patient contact material as the Karl Storz Video Gastroscope System (K060907)

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards.

The 6VT--D Transducer and its applications comply with voluntary standards:

1. IEC60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety
2. IEC60601-1-2,Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests
3. IEC60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment
4. NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment when connected to a GE Ultrasound System
5. ISO10993-1, Biological Evaluation of Medical Devices-

6. NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment when connected to a GE Ultrasound System
7. ISO14971, Application of risk management to medical devices

The following quality assurance measures were applied to the development of the complete medical system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, 6VT-D Transducer, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the 6VT-D Transducer to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

GE VINGMED ULTRASOUND AS
% Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 W. Innovation Drive, RP-2138
WAUWATOSA WI 53226

Re: K141093
Trade/Device Name: 6VT-D Diagnostic Ultrasound Transducer
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: April 25, 2014
Received: April 28, 2014

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

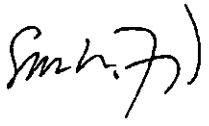
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141093

Device Name
6VT-D Diagnostic Ultrasound Transducer

Indications for Use *(Describe)*

6VT-D is intended for use by a qualified physician for use with GE Diagnostic Ultrasound Systems for ultrasound evaluation of Cardiac anatomy of adults through Transesophageal means of access, having imaging capabilities in 2D as well as in real-time 3D / 4D mode.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use Form

6VT-D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/ Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	RT3D Mode*
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac	P	P	P	P	P	P	P	P	P	P	P
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	P
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
[*] RT3D is Realtime 3D / 4D volume tissue scan acquisition (with or w/o color flow);

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)